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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,936	08/05/2003	David Michael Goldstein	R0145B-REG	3264

7590 09/03/2004

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EXAMINER

NWAONICHA, CHUKWUMA O

ART UNIT PAPER NUMBER

1621

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

10/634,936

Applicant(s)

GOLDSTEIN ET AL.

Examiner

Chukwuma O. Nwaonicha

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-15 are pending in the application.

Election/Restrictions

Applicants' election, filed on 7/7/04 with traverse of Group I is acknowledged. The traversal is on the ground(s) that Groups:

- I. Claims 1-15, drawn to compounds according to claim 1 wherein **Z** is **carbon**, classified in class 546, subclass 122+,
- II. Claims 1-15, drawn to compounds according to claim 1 wherein **Z** is **nitrogen**, classified in class 544, subclass 253,
- III. Claim 16-18, drawn to method of use or treatment wherein **Z** is **carbon**, classified in class 514, subclass 299+,
- IV. Claim 16-18, drawn to method of use or treatment wherein **Z** is **nitrogen**, classified in class 514, subclass 299+

are not independent and patentably distinct inventions because there is a relationship and co-action among Groups I and IV. The traversal was not found persuasive because Group I has a different structural carbon back bone with respect to Group II, and is used as inhibitor of protein tyrosine kinase (PTK) and cell cycle kinase mediated cellular proliferation as disclosed in US 6,150,359.

Inventions of Groups I and IV are related as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process for using the product as claimed can be practiced with another materially different product or (2) that the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

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In the instant case the process of using the product as claimed can be practiced with another materially different product, such products are disclosed in US 6,451,804, 6,506,749, WO 96/34867 WO 98/33798 and WO 96/15128 for example.

Inventions of Groups II and III are related as product and method of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) that the process for using the product as claimed can be practiced with another materially different product or (2) that the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using the product as claimed can be practiced with another materially different product, such products are disclosed in US 6,451,804, 6,506,749, US 6,150,359, WO 96/34867, WO 98/33798 and WO 96/15128 for example.

Groups I, III and V are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Groups, there being no allowable generic or linking claim. All claims consisting of Group II: claims 1-15 will be examined on the merits in turn. Applicants are reminded of their right to file divisional applications to the non-elected claims.

Restriction is made final.

Applicants' are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship

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must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Specification

The specification is objected to because the nitrogen in the structures shown on lines: 10, 20 of page 29, line 10 of page 30, line 7 of page 35 and line 5 of page 38 of the specification has no proton/two bonds instead of three bonds. Correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

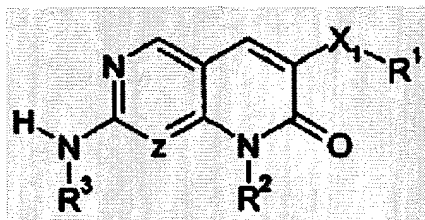
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Boschelli et al., {WO 98/33798}.

Applicants claim a 6-alkoxy-pyrido-pyrimidine of general formula I and its pharmaceutically acceptable salt, hydrate or prodrug:

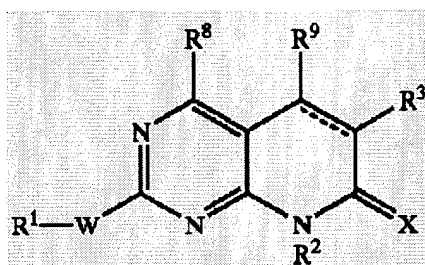
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I

wherein **Z** is **nitrogen** and all other variables are as defined in the claims.

Boschelli et al. disclose pyridopyrimidine of general formula II.



II

The compounds of Boschelli et al. anticipate the genus of claims 1, 10 and 13 when **W** is NH, **X** is O, **R**¹ is C₁-C₁₀ alkyl or (CH₂)_nheterocyclyl, **R**² is hydrogen, C₁-C₁₀ alkyl or C₃-C₁₀ cycloalkyl, **R**³ is NR⁴R⁵ or OR⁴, **R**⁴ and **R**⁵ independently are hydrogen, C₃-C₁₀ cycloalkyl, or substituted alkyl, **R**⁸ is hydrogen, **R**⁹ is hydrogen, the dotted line represents a double bond and n is 0. See pages 4-5 of WO 98/33798.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Boschelli et al., {WO 98/33798}. Boschelli et al. patent discloses and claims pyridopyrimidine compound wherein **X** (general formula II) is O. See pages 4-5 of WO 98/33798.

Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by Boschelli et al., {WO 98/33798}. Boschelli et al. patent discloses and claims

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pyridopyrimidine compound wherein R^3 (general formula II) is OR^4 and R^4 is a C_3 - C_{10} cycloalkyl. See pages 4-5 of WO 98/33798.

Claims 4, 5, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Boschelli et al., {WO 98/33798}. Boschelli et al. patent discloses and claims pyridopyrimidine compound wherein R^1 (general formula II) is $(CH_2)_n$ heterocyclyl, C_3 - C_{10} cycloalkyl or C_1 - C_{10} alkyl; wherein the alkyl is optionally substituted by hydroxyl or alkoxy and n is 0. See pages 4-5 of WO 98/33798.

Claims 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Boschelli et al., {WO 98/33798}. Boschelli et al. patent discloses and claims pyridopyrimidine compound wherein R^2 (general formula II) is hydrogen or C_1 - C_{10} alkyl; wherein the alkyl is optionally substituted by hydroxyl. See pages 4-5 of WO 98/33798.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Boschelli et al., {WO 98/33798}. Boschelli et al. patent discloses compound of claim 1 and its acceptable salt. See pages 4 and 150 of WO 98/33798.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

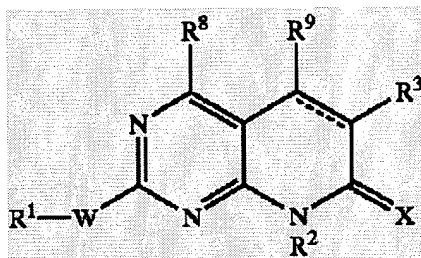
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1-10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Boschelli et al {U. S. Pat. 6,498,163}.

Boschelli et al. teach pyridopyrimidines of general formula III.



The genus of claims 1, 10 and 13 are anticipated by Boschelli et al. anticipate the genus when **W** is NH, **X** is O, **R¹** is C₁-C₁₀ alkyl or (CH₂)_nheterocyclyl, **R²** is hydrogen, C₁-C₁₀ alkyl or C₃-C₁₀ cycloalkyl, **R³** is NR⁴R⁵ or OR⁴, **R⁴** and **R⁵** independently are hydrogen, substituted alkyl or C₁-C₁₀ alkyl, **R⁸** is hydrogen, **R⁹** is hydrogen, the dotted line represents a double bond and n is 0. See pages 3-4 of U. S. Pat. 6,498,163.

Allowable Subject Matter

Claims 11, 12 and 14 are objected to as being dependent upon a rejected base claims (claims 1, 10 and 13), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

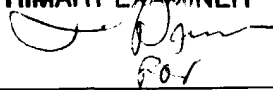
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chukwuma O. Nwaonicha, Ph.D.
Patent Examiner
Art Unit: 1621
August 17, 2004

J. PARSA
PRIMARY EXAMINER



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